

PILOT TES DATA ANALYSIS MEETING

Conference Room T2

MEETING AGENDA

May 21, 2001

Purpose: To assure that the Report and Analysis Plan addresses all objectives of the Pilot Study; to recap the descriptive Report and Analysis Plan; to describe the approach that will be used to determine inter- and intra individual variability; and to examine in detail the model building process.

8:30-8:45	Introduction, Purpose and Anticipated Outcomes	Nelson
8:45-9:15	Review of Descriptive Report and Analysis Plan	Chaouki
9:15-9:45	Variability Estimates: A Mixed Modeling Approach. <i>An example to illustrate the use of mixed model analyses to estimate inter-and intra-individual variability should be presented here.</i>	Gennings, Carter
9:45-10:30	Model Building for Dose Response Analysis 1: Defining potential candidate variables. <i>A list of all potential candidate variables should be presented here, with a rationale for their construction and/or use.</i>	Covance
10:30-10:45	BREAK	
10:45- Noon	Model Building for Dose Response Analysis 2: Identifying candidate variables for dose-response modeling. <i>Methodologies for refining the list of potential candidate variables will be presented, including regression tree analysis as one approach.</i>	Chaouki, Loh
Noon-1:00	LUNCH	
1:00-2:30	Model Building for Dose Response Analysis 3: Quasi-likelihood method to fit the dose-response model. <i>An example using Proc NLIN should be presented here, to illustrate the specific process steps and considerations for using quasi-likelihood methods to fit this model.</i>	Covance
2:30-2:45	BREAK	
2:45-4:00	Model Building for Dose Response Analysis 4: Model fit, validation, and inference about the model. <i>Methods for assessing the fit of the model, for validating the model, and inference using this model all should be presented here for clarity and for further discussion.</i>	Covance
4:00-4:30	Meeting the Objectives. <i>A final review of all proposed analyses, to determine how well they meet the study objectives.</i>	Gear
4:30-5:00	Next steps/Wrap-up	Nelson
NOTES:	Breaks of 15 minutes duration are scheduled at 10:30 p.m. and 2:30 p.m. Times are approximate, and are intended to serve as a guide only.	

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